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EXAMINER

ALAWADI, SARAH

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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Claims 24-25, 28, and 29-30 are rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants point out that the addition element of original claims 24 and 29 were elements of the claimed apparatus referred to as a means and thus must be a structural component to the apparatus.

In response the Examiner respectfully submits that original claims 24 and 29 recited a means for adding cross-linking agents, whereas the amended claims 06/23/2009 recite addition elements. It is not clear what an addition element is and if it imparts a structural limitation for the apparatus claim. The original claims do not have addition elements, but rather have a means for adding various reagents which could be numerous interpretations, open to mixing in a beaker contained in a water bath. If the cross-linking agent is the addition element it is not clear how the apparatus imparts that structure once the cross-linking agent is added because once the cross linking agent is added there is no more addition element. The Examiner respectfully submits that should Applicant's disclose that each addition element recited forms part of the apparatus, there is no support found in the specification for such an element, see reasons in office action mailed 11/19/2009. Support is found for adding cross-linking agents and polysaccharides; however such support does not impart any structural limitations to the apparatus and there is no teaching in the disclosure whether the addition elements are part of the instant apparatus or are intended to be ingredients added to a mixture.

Claims 24-25, and 28-30 are rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph as failing to comply with the written description requirement. The terms "air injector", "water supply" and "addition element" are considered new matter. Applicants argue that adding air to gelatin is well known in the art and that adding water to a mixture inherently requires a water supply. With regard to addition elements, Applicants submit paragraph 022 of the instant disclosure which states that "sugars and/or polysaccharides may be added to the gelatin" thus three elements may be used within the mixture, and thus at least three addition elements may be present in the apparatus.

In response, the Examiner respectfully submits that with regards to air injector, the instant claims filed 03/20/2009 recite a "means for adding air." There are numerous ways which add air to compositions; nowhere does the instant disclosure recite a structural element such as an air injector as included with the apparatus. With regards to "water supply" the originally filed claims recite a means for adding water but do not recite that a water supply is a necessity of the apparatus. Water can be added to composition numerous ways, but it is not described in the instant disclosure a "water supply". With regards to addition element, the instant disclosure recites sugars or polysaccharides may be added to the composition. However, Applicants are reminded that the claims are drawn to an apparatus not a composition in which water or other components are added. There is no description for an apparatus with the claimed structural components.

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Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. U.S. Patent 4,292,972 in view of Reich U.S. Patent 6,706,690. Applicants argue that Pawelchack et al. does not disclose a heat source capable of heating a mixture and expressly freeze dries the material, and that Pawelchack et al. uses carboxymethylcellulose which is known to be soluble in water. Applicants further point out that the claimed dryer is separate from the claimed heat source and both must be present in the apparatus.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein the claimed dryer is separate from the claimed heat source or the exclusion of carboxymethylcellulose from the composition), are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With regards to Applicants arguments that Pawelchack et al. does not disclose a heat source capable of heating a mixture, the Examiner submits column 4, lines 43-46 which discloses that the compositions can be prepared at room temperature or at elevated temperatures, thus the presence of a heat source is inherent when preparing the mixture with elevated temperatures, after which becomes freeze dried. The material is then lyophilized through use of a vacuum in order to dry, see column 4, lines 65-68. With regards to heating Reich et al. was relied upon to teach alternate methods of drying hemostatic materials such as freeze-drying, heat drying or spray drying, see column 4, lines 67-column 5 line 3. Heat drying would inherently require a heating element. Secondly, as Pawelchack teach blowing air into the mixture, and it is taught that mixing the ingredients can occur at elevated temperatures it would be obvious to the skilled artisan to include a heat source for mixing or for heating the air.

Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al. U.S. Patent 5,894,022 in view of Szymaitis U.S. Publication No. 2003/0194380. Applicants argue that Ji et al. does not appear to disclose a mixing chamber or mixing element capable of stirring the contents of the mixing chamber, Rather Ji et al. appears to disclose that a mixture exists. The composition of Ji et al. does not disclose or require the apparatus of the pending claims. Applicants argue that Ji et al. does not appear to disclose a dryer operating at a temperature above freezing or drying the composition. Applicants further argue that Ji et al. does not disclose or suggest injecting air into the composition for foaming which was relied upon by Szymaitis. Applicants note that the injecting air as to foam a composition would appear to defeat the purpose of precipitating a matrix base by heating an emulsion, thus rendering the composition unsuitable for its intended purpose. Applicants argue that Szymaitis does not appear to teach a haemostatic composition, or a method or apparatus for forming one. Lastly, Applicants argue that neither Ji et al. nor Szymaitis appear to disclose or suggest an air injector as part of an apparatus for forming a haemostatic material.

In response, the Examiner submits that Ji et al. teaches compositions which form a gel that are heated in a water bath which is a chamber. The compositions include hemostatics, column 3 line 8. The matrix composition taught by Ji can include addition elements such as gelatin, cross-linking agents, starch (polysaccharide) albumin (clot formation accelerator) and stabilizers see

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column 7, lines 55-67. The composition can be prepared by heating, mixing and dissolving reagents see column 7, lines 55-67. Thus as reagents are prepared by heating, mixing and dissolving, it is inherent that the composition is being mixed by an apparatus. Regarding adding air to the composition of Ji and drying, Ji et al. teaches the forming of sponges, thus it is inherent that the consistency of the sponge contains air pockets. Further Zi et al. teach that the sponges are used to create hemostasis, see paragraph 016. Zi et al. does not expressly teach a dryer, however Szymaitis et al. discloses that the prior art teaches that sponges are formed when dried, see paragraph 048 thus it is inherent that the sponges are dried. Szymaitis also teaches sponges or gauzes, See paragraph 016. The Examiner respectfully submits that injecting air would not defeat the purpose of precipitating a matrix base by heating an emulsion, because Ji et al. expressly teaches semi-solid or sponge textures. It is well known in the art that sponges contain air pockets. As both Szymaitis and Ji teach sponges there would have been a reasonable expectation of success for injecting air into the composition taught by Zi as Zi also teaches haemostatic agents and the use of sponges.

/Shanon A. Foley/

Primary Examiner, Art Unit 1619